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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/678,594	10/03/2003	Corey S. Maas	021993-000100US	6160

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EXAMINER	
TYSON, MELANIE RUANO	

ART UNIT	PAPER NUMBER
3731	

DATE MAILED: 09/21/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	**Application No.** 10/678,594	**Applicant(s)** MAAS ET AL.	
	Examiner Melanie Tyson	**Art Unit** 3731	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE _3_ MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _22 August 2006_.
2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.
3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) _1-7_ is/are pending in the application.
4a) Of the above claim(s) _____ is/are withdrawn from consideration.
5)☐ Claim(s) _____ is/are allowed.
6)☒ Claim(s) _1-7_ is/are rejected.
7)☐ Claim(s) _____ is/are objected to.
8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.
10)☒ The drawing(s) filed on _22 August 2006_ is/are: a)☒ accepted or b)☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a)☐ All b)☐ Some * c)☐ None of:
1.☐ Certified copies of the priority documents have been received.
2.☐ Certified copies of the priority documents have been received in Application No. _____.
3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

This action is in response to applicant's amendment received on 22 August 2006.

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

2. The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

   1. Determining the scope and contents of the prior art.
   2. Ascertaining the differences between the prior art and the claims at issue.
   3. Resolving the level of ordinary skill in the pertinent art.
   4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

3. Claims 1, 3, and 6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sasaki et al. (Meloplication of the Malar Fat Pads by Percutaneous Cable-Suture Technique for Midface Rejuvenation: Outcome Study; Plastic and Reconstructive Surgery Vol. 110 No. 2, pp. 635-654; August 2002), in view of Greenstein (Patent No. 5,964,773).

Regarding claim 1, Sasaki et al. disclose a surgical device for suspending soft tissue to correct midface ptosis comprising first and second shafts (Figure 4, two needles). Figure 4 shows the first and second shafts are rigid and straight, and each shaft has a distal end (top portion) and a proximal end (bottom portion). Sasaki et al.

disclose first (suspension) and second (tissue-release or braided; pg. 640, fourth paragraph) sutures. Each suture has a first (attached to proximal end of first shaft) and a second (attached to proximal end of second shaft) end. Figure 4 shows an anchor graft attached to the first (suspension) suture. Regarding claim 6, Sasaki et al. disclose the suspension suture is a monofilament suture (PROLENE; pg. 639, third paragraph), and the tissue-release suture is a braided suture (pg. 639, third paragraph and pg. 640, fourth paragraph).

Regarding claim 1, Sasaki et al. do not disclose the ends of the sutures are fused to the proximal end of the shafts and regarding claim 3, Sasaki et al. do not disclose the proximal ends of the shafts are swedged to the ends of the sutures. Greenstein teaches "fusing" the ends of a suture (Figure 1, element 22) to the proximal end (bottom portion) of a shaft (21) by way of deforming the shaft (21) adjacent the suture (22) and achieving a clamping action on the suture (22; column 3, lines 9-12). Regarding claim 3, Greenstein discloses the deformation described above can be achieved by swedging, peening, or other known methods (column 3, lines 9-13). Greenstein discloses "fusing", or swedging, a suture to a shaft is done in order to secure the suture to the shaft (column 1, lines 63-65), in turn providing an improved insertion device (column 1, lines 60-63). Therefore, to construct the surgical device of Sasaki et al., where the sutures are fused to the proximal end of the shafts and the shaft is swedged on the ends of the sutures as taught by Greenstein, would have been obvious to one of ordinary skill in the art at the time the invention was made so that the suture remains secured to the shaft during use.

4. Claim 2 is rejected under 35 U.S.C. 103(a) as being unpatentable over Sasaki et al. in view of Greenstein as applied to the claims above, and further in view of Cappucci (Patent No. 5,098,389).

Sasaki et al. in view of Greenstein disclose a surgical device as described above; however Sasaki et al. in view of Greenstein do not disclose a blunt tip on each shaft. Cappucci discloses a straight and rigid shaft (Figure 1, element 18) terminating in a blunt tip (spherical distal end, 19) in order to provide maximum safety (column 3, lines 6-8) during a procedure involving tissue penetration, since a blunt tip reduces the danger of damaging a nerve, blood vessel, or other tissue (column 1, lines 23-25). Therefore, to construct the first and second shafts of Sasaki et al. in view of Greenstein with a blunt tip as taught by Cappucci would have been obvious to one of ordinary skill in the art at the time the invention was made in order to maximize safety and reduce the risk of damaging surrounding nerves and tissue during the procedure.

5. Claims 4-5 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sasaki et al. in view of Greenstein as applied to the claims above, and further in view of Bonutti (Patent No. 5,403,348).

Regarding claims 4-5, Sasaki et al. in view of Greenstein disclose a surgical device as described above, wherein the anchor graft is a microporous fluorocarbon polymer (GORE-TEX, pg. 639, third paragraph); however, Sasaki et al. in view of Greenstein do not disclose a toroidal anchor. Like Sasaki et al. in view of Greenstein, Bonutti discloses a suture anchor. Unlike Sasaki et al. in view of Greenstein, Figure 1 of Bonutti shows the suture anchor (10) is toroidal (doughnut shaped) in order to facilitate anchor to tissue attachment, which in turn holds the suture firmly in place (column 1, lines 17-19). Therefore, to construct the anchor of Sasaki et al. in view of Greenstein in a toroidal shape as taught by Bonutti would have been obvious to one of ordinary skill in the art at the time the invention was made in order to secure the suture in place.

6. Claim 7 is rejected under 35 U.S.C. 103(a) as being unpatentable over Sasaki et al. in view of Greenstein as applied to the claims above, and further in view of Yoon (Patent No. 5,849,019).

Sasaki et al. in view of Greenstein disclose a surgical device as described above; however, Sasaki et al. in view of Greenstein do not disclose a manually releasable clamp to receive the first and second ends of one of the sutures. Yoon discloses a manually (column 7, lines 47-49) releasable clamp (Figure 1, element 10) that can receive the first and second ends of a suture (Figure 8) in order to effect a knot for a stitch formed with the suture material (column 6, lines 6-10). Therefore, to construct the device of Sasaki et al. in view of Greenstein with a manually releasable clamp as taught by Yoon would have been obvious to one of ordinary skill in the art at the time the invention was made in order to maintain the suture in place.

Response to Arguments

7. Applicant's arguments filed 22 August 2006 have been fully considered but they are not persuasive. Applicant argues primarily that the references cited by the examiner do not disclose all of the limitations. In response to applicant's argument, Sasaki et al. in view of Greenstein disclose all of the limitations set forth in claims 1, 3, and 6 (see rejections above). Greenstein is cited merely to provide the teaching of "swedging"

sutures to shafts and to show that "swedging" is a fusion technique well known in the art. Sasaki et al. disclose *two sutures* attached to the *end* of a single shaft, and to attach the *two sutures* of Sasaki et al. by a well known fusion technique, such as the one taught by Greenstein, would have been obvious to one of ordinary skill in the art at the time the invention was made in order to ensure the sutures are secured to the shafts (see rejections above). Furthermore, to clarify the "bottom" (or proximal end) of the shaft of Greenstein, it consists of everything adjacent the pointed tip (or distal end) and down. Claims in a pending application should be given their broadest reasonable interpretation. See *In re Pearson*, 181 USPQ 641 (CCPA 1974). Therefore, the suture is fused to the "proximal end" of each shaft.

8. Applicant further argues that the shaft disclosed by Capucci bears no relation to the shaft recited in the claims and that Capucci is not in the same field of applicant's endeavor (equipment or procedures used in performing tissue suspension to correct midface ptosis). In response to applicant's argument, the shaft disclosed by Capucci does relate to the shaft recited in the claims: it terminates in a blunt tip and it is utilized to penetrate soft tissue. Capucci is cited merely to provide the teaching of providing a blunt tip on the terminal end of a shaft, thus showing that it is well known in the art to do so. The purpose of the "introducer needle" is merely to facilitate skin penetration (column 1, lines 62-66). The blunt tipped shaft is utilized to advance into the muscle (retrobulbar; column 5, lines 43-45), since the blunt end provides a lower risk of damaging nerves or blood vessels within the tissue (column 1, lines 23-25). In the case where skin penetration is not required, such as midface ptosis, the blunt tipped shaft

would be functional without utilizing an "introducer needle". Therefore, to construct the shaft of Sasaki et al. terminating in a blunt tip as taught by Capucci would have been obvious to one of ordinary skill in the art at the time the invention was made in order to minimize damage (see rejection above).

Furthermore, although Capucci is not in the same field of applicant's endeavor, Capucci is deemed analogous art. It has been held that a prior art reference must either be in the field of applicant's endeavor or, if not, then be reasonably pertinent to the particular problem with which the applicant was concerned, in order to be relied upon as a basis for rejection of the claimed invention. See *In re Oetiker*, 977 F.2d 1443, 24 USPQ2d 1443 (Fed. Cir. 1992). In this case, the blunt tipped shaft of Capucci solves the same problem with which the applicant was concerned: penetrating soft tissue without damaging nerves or blood vessels within the tissue. Therefore, Capucci is deemed analogous art and may be relied upon as a basis for rejection of the claimed invention.

9. Since claims 2-7 depend on claim 1, the responses detailed above with respect to claim 1 also apply to claims 2-7.

Conclusion

10. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within

TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Melanie Tyson whose telephone number is (571) 272-9062. The examiner can normally be reached on Monday through Thursday 7:30 a.m. - 5:00 p.m., alternate Fridays 7:30 a.m. - 4:00 p.m. EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anhtuan Nguyen can be reached on (571) 272-4963. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a

USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Melanie Tyson MT
September 14, 2006

ANHTUAN T. NGUYEN
SUPERVISORY PATENT EXAMINER
9/18/06.